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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/771,241

02/03/2004

Judith Zyskind

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09/07/2006

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EXAMINER

SKIBINSKY, ANNA

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,241	ZYSKIND ET AL.	
	Examiner	Art Unit	
	Anna Skibinsky	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 28-32, drawn to expressing in a cell an antisense nucleic acid, contacting a cell with an agent which reduces activity, contacting a cell with a candidate compound, and determining whether said sensitized cell with a candidate compound inhibits proliferation, classified in class 436, subclass 6.

If this Group is selected the below listed specie election from each of Species A and B is required.

II. Claims 11-27, drawn to identifying an inhibitory nucleic acid sequence which inhibits proliferation in a microorganism, contacting a second microorganism with a proliferation-inhibiting amount of nucleic acid and determining in which of two types of microorganisms the candidate compound inhibits the proliferation more, classified in class 435, subclass 6.

If this Group is selected the below listed specie election from each of Species C, D and E is required.

The inventions are independent or distinct, each from the other because:

Group I is a method that includes the expressing of an antisense nucleic acid against a nucleic acid encoding a proliferation-required gene product to produce a sensitized cell. Group II is a method that requires identifying a gene or gene product required for proliferation in a first

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microorganism and identifying a homolog of the gene or gene product in a second microorganism. Thus the subject matter of Groups I and II are distinct and would entail an undue search burden since Group I and II are distinct methods for screening a candidate compound.

Specie Election Regarding Group I

This application contains claims directed to the following patentably distinct species. An election from each of species A and B is required:

Specie A

A1: wherein said gene produce is a polypeptide (e.g. claim 5)

A2: wherein said gene product is an RNA (e.g. claim 6).

These species are distinct because they are drawn to different biochemical structures are classified and studied separately, presenting a distinct search burden which is undue if searched together.

Currently claims 1-4, 7-10, and 28-32 are generic to this species.

Specie B

Wherein said agent which reduces activity or level of a gene product required for proliferation of said cell comprises an

B1: antisense nucleic acid (e.g. claim 29)

B2: antibiotic (e.g. claim 30)

These species are distinct because they are drawn to different forms of agents directed at the reduction of activity in a cell which are classified and studied separately, presenting a distinct search burden which is undue if searched together.

Currently claims 1-10, 28, and, 31-31 are generic to this species.

Specie Election Regarding Group II

This application contains claims directed to the following patentably distinct species. An election from each of species C, D and E is required:

Specie C

Wherein said inhibitory nucleic acid comprises an antisense nucleic acid

C1: to a portion of said homolog (e.g. claim 17)

C2: to a portion of the operon encoding said homolog (e.g. claim 18)

These species are distinct because they are drawn to different biochemical structures which different functions and structures which are classified and studied separately, presenting a distinct search burden which is undue if searched together.

Currently claims 11-16 and 19-27 are generic to this species.

Specie D

Wherein the step of contacting the second microorganism with a proliferation-inhibiting amount of said nucleic acid sequence comprises

D1: directly contacting said second microorganism with said nucleic acid (e.g. claim 19)

D2: expressing an antisense nucleic acid to said homolog in said second microorganism (e.g. claim 20).

These species are distinct because they are drawn to different methods for introducing the nucleic acid into the microorganism which are classified and studied separately, presenting a distinct search burden which is undue if searched together.

Currently claims 11-18 and 21-27 are generic to this species.

Specie E

Wherein said inhibitory nucleic acid comprises

E1: a portion of an antisense nucleic acid which inhibits the proliferation of said first microorganism (e.g. claim 24).

E2: an antisense molecule against the entire coding region of the gene involved in proliferation of the first microorganism (e.g. claim 25)

E3: an antisense nucleic acid to a portion of the operon encoding the gene involved in proliferation of the first microorganism (e.g. claim 26).

These species are distinct because they are drawn to different structures and functions of the nucleic acid which are classified and studied separately, presenting a distinct search burden which is undue if searched together.

Currently, claims 11-23 and 27 are generic to this species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0188. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Anna Skibinsky, PhD



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